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EXAMINER

PENG, KUO LIANG

ART UNIT PAPER NUMBER

1712

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,742

Applicant(s)

GUNATILLAKE ET AL.

Examiner

Kuo-Liang Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/7/03 Response.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 77-152 is/are pending in the application.
- 4a) Of the above claim(s) 133-136 and 147-151 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 77-93, 101-132, 137-146 and 152 is/are rejected.
- 7) ☒ Claim(s) 77-132, 137-146 and 152 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: English translation of JP 63-179916.

DETAILED ACTION

1. The Applicants' response to restriction requirement filed on July 7, 2003 was received.
2. Applicant's election with traverse of Group I, Claims 77-132, 137-145, 146 and 152, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that "The restriction requirement is traversed on the basis that the search and examination of the claims of Groups II and III can be made without serious burden on the Office". This is not found persuasive because of the following reasons: As mentioned previously in the restriction requirement, inventions of Group I and Group II are related as process of making and product made. The shape memory polymer of Group I can be prepared by reacting component b) and component c) to form a prepolymer and subsequently reacting the prepolymer with component a). Inventions of Group I and Group III are related as mutually exclusive species in an intermediate-final product relationship. The intermediate product of Group I is deemed to be useful as a coating material and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

Therefore, Claims II and III are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The requirement for Claim III is still deemed proper and is therefore made FINAL.

If the invention of Group I is later found patentable, Examiner would then consider rejoin the invention of Group II with the invention of Group I.

Claim Objections

3. Claims 77-132, 137-146 and 152 are objected to because of the following informalities:

In Claim 77 (line 13), should "(d)" be -- (b) -- ?

In Claim 84 (line 2), after "polysiloxane", should there be -- macrodiol --?

In Claim 84 (line 8), should "A and A' are as defined in claim 77:" be removed?

In Claim 84 (line 13), before "radical", should there be -- divalent --?

In Claim 88 (line 3), should "and R₅ and R₆ are defined in Claim 87" be removed?

In Claim 86 (line 3), should "R and R'" be -- A and A' --?

Claim 87 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 87 does not further limit the subject matter of Claim 86.

In Claim 88 (line 3), should "and R₅ and R₆ are as defined in Claim 87" be removed?

In Claim 92 (line 3), should "A is" be -- A and A' are --?

In Claim 94 (page 7, lines 4-5), should there is an "O" at the carbonate linkage?

In Claim 94 (page 7, line 11), should the definition of R₁ to R₇ be explicitly expressed?

In Claim 94 (page 7, line 14), should "A and A' are defined" Be removed?

In Claim 96 (last line), should "wherein R₁ to R₉,claim 18" be removed?

In Claim 101 (last two lines), should "in claim 77" be removed?

In Claim 116 (lines 7-8), should the definition of R₁ to R₇ be explicitly expressed?

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Claim 146 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claim does not exclude the possibility of the use of the shape memory polymer or the composition thereof in the purposes other than the purpose of recited "when usedresistance".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 145 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 84-93, 105-108, 116, 132 and 145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 84 (line 9), "R₅" and "R₆" cannot be monovalent radicals.

In Claim 84 (line 2), when R₇ is not an oxygen atom, the two terms "polysiloxane" cause confusion because there are no siloxane units.

In Claim 94 (page 7, line 12), "R₈" and "R₉" cannot be monovalent radicals.

Claim 116 recites the limitation "q" in the last line. There is insufficient antecedent basis for this limitation in the claim.

In Claim 132 (line 2), "a non-elastomeric polyurethane or polyurethane-urea" causes confusion because typically a polyurethane or polyurethane-urea is considered an elastomer only.

Claim 145 provide for the use of a shape memory polymer or a composition thereof, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 77-91, 101-113, 115-121, 137-146 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunatillake (WO 99/03863).

With respect to Claims 77-91, 101-108 and 117-121, Gunatillake discloses a polyurethane composition comprising a polyurethane derived from i) a soft segment macrodiol, ii) a diisocyanate and iii) a chain extender or a chain extender composition. The soft segment macrodiol can be polyethers, polyesters, polysiloxanes, polycarbonates or mixtures thereof, as further exemplified in Examples. (page 3, line 25 to page 4, line 10, page 10, line 13 to page 11, line 9). The polysiloxane macrodiol can have a molecular weight of 200 to 5000, preferably 300 to 1200 (page 10, line 23 to page 11, line 1). The polyether macrodiols can be those described in page 11, lines 2 to 13 and Examples. The Gunatillake's polyurethane is substantially the same as that of the present invention. Therefore, Examiner has a reasonable basis to believe that Gunatillake's polyurethane inherently has the shape memory properties as those of Applicants'. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to Applicants to show otherwise. *In re Best*, 195 USPQ 430 (CCPA 1977).

With respect to Claims 109-111, the diisocyanate can be those described in page 11, lines 14-20.

With respect to Claims 112-113 and 115-116, the chain extender can be the one described in page 4, lines 1-10, wherein R₇ can be the one described in page 4, lines 6-8 and page 7, lines 24-26. It can be used in combination with another chain extender such as 1,4-butanediol, etc. (page 9, lines 3-12).

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With respect to Claims 137-146 and 152, the polyurethane composition has improved mechanical properties, clarity, processability, biostability and/or degradation resistance (page 13, line 11 to page 15, line 17).

10. Claims 77, 81-82, 101-104, 109-113, 117-121, 123-124, 137-146 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi832 (US 5 139 832).

With respect to Claims 77, 81-82, 101-104, 109-113 and 117-121, Hayashi832 discloses a shape memory polyurethane (col. 2, line 25 to col. 3, line 27 and Examples).

With respect to Claims 123-124, the glass transition temperature of the polyurethane can be 40°C (Embodiment 3).

With respect to Claims 137-146 and 152, since Hayashi832's polyurethane reads on Applicants' polyurethane, it should inherently have the same properties possessed by Applicants' polyurethane, and they can be used in the same application. *In re Best*, 195 USPQ 430 (CCPA 1977).

11. Claims 77, 81-82, 101-104, 109-113, 117-121, 123-128, 137-146 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi591 (US 5 049 591).

With respect to Claims 77, 81-82, 101-104, 109-113 and 117-121, Hayashi591 discloses a shape memory polyurethane (col. 2, line 22 to col. 3, line 21 and Examples).

With respect to Claims 123-124, the glass transition temperature of the polyurethane can be 23, 25 or 26°C (Table 1).

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With respect to Claims 125-128, a blowing agent can be used in combination with the shape memory polyurethane (col. 3, line 40 to col. 4, line 10).

With respect to Claims 137-146 and 152, since Hayashi591's polyurethane reads on Applicants' polyurethane, it should inherently have the same properties possessed by Applicants' polyurethane, and they can be used in the same application. *In re Best*, 195 USPQ 430 (CCPA 1977).

12. Claims 77-84, 85, 90-91, 101-104, 109-110, 112-114, 117-121, 125-128, 137-146 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Pudleiner (US 5 430 121).

With respect to Claims 77-84, 85, 90-91, 109-110, 112-114 and 117-121, Pudleiner discloses a polyurethane described in col. 4, lines 3-53 and Examples, wherein a mixture of macrodiol (i.e., components a) and d)) can be used. Note that the polyurethane has an end-capping groups of polyester-OH. The polysiloxane based macrodiol of formula (I) can have one to 30 of dialkylsiloxane repeating units and 1 to 50 ester repeating units (col. 4, lines 25-42). The organic diisocyanates can be cyclohexane diisocyanate, isophorone diisocyanate, etc. (col. 5, line 63 to col. 6, line 5). The chain extender can be a butanediol, etc. (col. 6, lines 6-32). Pudleiner's polyurethane is substantially the same as that of the present invention. Therefore, Examiner has a reasonable basis to believe that Pudleiner's polyurethane inherently has the shape memory properties as those of Applicants'. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to Applicants to show otherwise. *In re Best*, 195 USPQ 430 (CCPA 1977).

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With respect to Claims 101-104, a polyether diol can be used (col. 4, lines 43-46, col. 4, line 67 to col. 5, line 22).

With respect to Claims 125-128, the polyurethane can be used in combination with other thermoplastics (col. 8, lines 30-36).

With respect to Claims 137-146 and 152, since Pudleiner's polyurethane reads on Applicants' polyurethane, it should inherently have the same properties possessed by Applicants' polyurethane, and they can be used in the same application. *In re Best*, 195 USPQ 430 (CCPA 1977).

13. Claims 77, 81-82, 101-104, 109-114, 117-121, 125-129, 137-146 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Meijs858 (US 5 393 858).

With respect to Claims 77, 81-82, 101-104 and 117-121, Meijs858 discloses a polyurethane or polyurethane-urea elastomeric composition wherein a single macrodiol or a mixture of macrodiols can be used (col. 2, line 50 to col. 3, line 41). Meijs858' polyurethane is substantially the same as that of the present invention. Therefore, Examiner has a reasonable basis to believe that Meijs858' polyurethane inherently has the shape memory properties as those of Applicants'. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to Applicants to show otherwise. *In re Best*, 195 USPQ 430 (CCPA 1977).

With respect to Claims 109-111, diisocyanates such as MDI, etc. can be used (col. 3, lines 9-41).

With respect to Claims 112-114, chain extenders such as butanediol, etc. can be used (col. 3, lines 36-41).

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With respect to Claims 125-129, the polyurethane or polyurethane-urea can be used in combination with a polysiloxane-containing polymer or oligomer, a crosslinking agent, catalysts, antioxidants, etc. (col. 3, lines 42-56). Note that the glass transition temperature of a typical polysiloxane containing polymer or oligomer than that of a polyether based polyurethane or polyurethane-urea.

With respect to Claims 137-146 and 152, since Meijs858' polyurethane reads on Applicants' polyurethane, it should inherently have the same properties possessed by Applicants' polyurethane, and they can be used in the same application. *In re Best*, 195 USPQ 430 (CCPA 1977).

14. Claims 77-93, 101-106, 108-114, 117-121, 125-128, 137-146 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Hideyuki (JP 04-248826).

With respect to Claims 77-93 and 117-121, Hideyuki discloses a polyurethane or polyurethane-urea by reacting a polysiloxane containing terminal hydroxyl or amino groups, a diisocyanate and a polyether polyol containing a tertiary amino group (another macrodiol) ([0011], [0014]-[0016], [0031] and Examples). Hideyuki's polyurethane or polyurethane-urea is substantially the same as that of the present invention. Therefore, Examiner has a reasonable basis to believe that Hideyuki's polyurethane inherently has the shape memory properties as those of Applicants'. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to Applicants to show otherwise. *In re Best*, 195 USPQ 430 (CCPA 1977).

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With respect to Claims 101-106 and 108, high molecular weight of oxyalkylene glycol such as polytetramethylene glycol, etc. can be used ([0019] and [0021]-[0022]).

With respect to Claims 109-111, a diisocyanate such as 4,4'-diphenylmethane diisocyanate (MDI), etc. can be used ([0012]).

With respect to Claims 112-114, a chain extender can be used ([0021]-[0022]).

With respect to Claims 125-128, the polyurethane or polyurethane-urea can be used in combination with heparin or a similar compound ([0027]). The typical glass transition temperature of a polyurethane or polyurethane-urea is different than that of a heparin.

With respect to Claims 137-146 and 152, since Hideyuki' polyurethane or polyurethane-urea reads on Applicants' polyurethane or polyurethane-urea, it should inherently have the same properties possessed by Applicants' polyurethane, and they can be used in the same application. *In re Best*, 195 USPQ 430 (CCPA 1977).

15. Claims 77-91, 101-106, 108-114, 117-121, 125-126, 128, 137-146 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito (JP 63-179916).

The page numbers and paragraph numbers appearing in the instant paragraph is based on the English translation of the corresponding JP patent.

With respect to Claims 77-91, 101-106, 108 and 117-121, Ito discloses a polyurethane which is a product of a polysiloxane diol, a polyoxy tetramethylene glycol, an aliphatic diisocyanate, an aliphatic diamine (i.e., chain extender) and optionally another diol which is other than the aforementioned diols/glycol. The polysiloxane diol can be represented by formula (1) (page 4, last paragraph to page 7, first paragraph and Examples). Ito's polyurethane is

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substantially the same as that of the present invention. Therefore, Examiner has a reasonable basis to believe that Ito's polyurethane inherently has the shape memory properties as those of Applicants'. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to Applicants to show otherwise. *In re Best*, 195 USPQ 430 (CCPA 1977).

With respect to Claims 109-111, the diisocyanate can be MDI, etc. (page 7, second paragraph).

With respect to Claims 112-114, the chain extender can be aliphatic diamine such as ethylene diamine, etc and/or a diol other than the aforementioned polysiloxane diol and polyoxy tetramethylene glycol, such as 1,3-butane diol, etc (page 7, third paragraph to page 8, first paragraph).

With respect to Claims 125-126 and 128, additives such as pigments, etc. can be added (page 9, second paragraph).

With respect to Claims 137-146 and 152, since Ito's polyurethane reads on Applicants' polyurethane, it should inherently have the same properties possessed by Applicants' polyurethane, and they can be used in the same application. *In re Best*, 195 USPQ 430 (CCPA 1977).

16. Claims 77-87, 88, 89,90, 91, 101-113, 117-121, 137-146 and 152 are rejected under 35 U.S.C. 102(b) as being anticipated by Meijs405 (WO 98/13405).

With respect to Claims 77-91 and 117-121, Meijs405 discloses a polyurethane composition including a reaction product of i) macrodiols including a) polysiloxane macrodiol and b) a polyether and/or polycarbonate macrodiol; ii) a diisocyanate and iii) a chain extender

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(page 13, lines 1-7). The polyether macrodiol can be represented by formula (II) (page 10, line 25 to page 11, line 2). The composition can comprise 70 to 90wt% of the polysiloxane macrodiol (col. 6, lines 23-26) which can be represented by formula (I) and have a molecular weight of 300 to 700 (page 7, line 1 to page 10, line 24). Hard segment can be 60 wt% (Tables 9-12).

Meijs405's polyurethane or polyurethane-urea is substantially the same as that of the present invention. Therefore, Examiner has a reasonable basis to believe that Meijs405's polyurethane inherently has the shape memory properties as those of Applicants'. Since PTO does not have proper means to conduct experiments, the burden of proof is now shifted to Applicants to show otherwise. *In re Best*, 195 USPQ 430 (CCPA 1977).

With respect to Claims 101-108, the polyether macrodiol can be represented by formula (II) (page 10, line 25 to page 11, line 24). More than one polysiloxane macrodiol can be used (page 4, lines 7-9).

With respect to Claims 109-111, the diisocyanate can be MDI, etc. (page 13, lines 8-14).

With respect to Claims 112-113, the chain extender can be 1,4-butanediol, etc. (page 13, lines 15-18).

With respect to Claims 137-146 and 152, the polyurethane composition has improved mechanical properties, clarity, processability, biostability and/or degradation resistance (page 4, line 2 to page 6, line 22).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunatillake.

Gunatillake discloses a shape memory polyurethane, supra, which is incorporated herein by reference. Gunatillake is silent the specific hardness in terms of Shore D and the specific glass transition temperatures of the polyurethane. Gunatillake further teaches the use of the materials in the field of application such as biomaterials (page 3, lines 19-24 and page 14, lines 13-18) wherein hardness and flexibility of the materials are obviously very important. Therefore, the hardness and glass transition temperature are Result-Effective variables. In light of which, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a polyurethane with whatever hardness and/or glass transition temperature through routine experimentation in order to obtain a proper polyurethane in the filed of application it will be used. Especially, Applicants do not show the criticalities of the specific hardness and the specific glass transition temperature. See MPEP 2144.05 (II).

19. Claims 77-91, 101-104, 105, 107, 109-113, 115-121, 137-146 and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 5 911 737) in view of Gunatillake.

Lee discloses a shape memory polyurethane-based material for medical devices, etc. (col. 2, lines 15-34, col. 3, lines 10-31 and col. 3, line 51 to col. 4, line 44). Lee is silent on the use of a specific type of the polyurethane. Gunatillake teaches the use of a polyurethane based materials

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for medical devices, etc., supra. The motivation of using Gunatllake's polyurethane based materials is to afford a material which has improved mechanical properties, clarity, processability, biostability and/or degradation resistance (page 13, line 11 to page 15, line 17). In light of the benefit mentioned, it would have been obvious to one of ordinary skill in the art at the time of invention to use Gunatllake's polyurethane based materials in Lee's disclosure.

20. Claim 122 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi832.

Hayashi832 discloses a shape memory polyurethane, supra, which is incorporated herein by reference. Hayashi832 is silent on the Shore D hardness of the polyurethane. Hayashi832 further teaches the use of the polyurethane to make a film that can have dead folds (col. 1, lines 48-63). As such, the hardness of the film is very important. In other words, the hardness of the polyurethane is a Result-Effective variable. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a polyurethane having whatever Shore D hardness through routine experimentation in order to afford an adequate film which have dead folds. Especially, Applicants do not show the criticality of the hardness of the polyurethane. See MPEP 2144.05 (II).

21. Claim 122 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pudleiner.

Pudleiner discloses a polyurethane, supra, which is incorporated herein by reference. Pudleiner is silent on the specific Shore D hardnesses below glass transition temperature and above glass transition temperature. However, Pudleiner teaches that the polyurethane can be used for making catheters and the hardness can be adjusted (col. 1, lines 7-10 and col. 6, lines 34-45).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adjust the hardness of Pudleiner's polyurethane through routine experimentation in order to obtain a material with adequate hardness for making catheters. Especially, Applicants do not show the criticality of the specific hardnesses. See MPEP 2144.05 (II).

22. Claims 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs858.

Meijs858 discloses a shape memory polyurethane or polyurethane-urea, supra, which is incorporated herein by reference. Meijs858 is silent the specific hardness in terms of Shore D and the specific glass transition temperatures of the polyurethane or polyurethane-urea. Meijs858 further teaches the use of the materials in the field of application the materials will be utilized, such as a biomaterial (col. 2, lines 1-49 and col. 3, line 67 to col. 4, lines 14) wherein the hardness and flexibility is important. Therefore, the hardness and glass transition temperature are Result-Effective variables. In light of which, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a polyurethane or polyurethane-urea with whatever hardness and/or glass transition temperature through routine experimentation in order to obtain a proper polyurethane or polyurethane-urea in the filed of application it will be used. Especially, Applicants do not show the criticalities of the specific hardness and the specific glass transition temperature. See MPEP 2144.05 (II).

23. Claims 107 and 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hideyuki.

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Hideyuki discloses a polyurethane or polyurethane-urea, supra, which is incorporated herein by reference.

With respect to Claim 107, Hideyuki is silent on the use of PHMO (polyhexamethyleneoxide). However, Hideyuki teaches the use of a polyalkyleneoxide. The polyalkyleneoxide is further exemplified as polytetramethylene glycol ([0019] and [0022]) which is a homologue of the PHMO. A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utility (i.e., in urethane or urea chemistry). "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See MPEP 2144.09.

With respect to Claims 122-124, Hideyuki is silent the specific hardness in terms of Shore D and the specific glass transition temperatures of the polyurethane or polyurethane-urea. Hideyuki further teaches the use of the materials for making thin film (abstract and [0001]) wherein the hardness and flexibility is important. Therefore, the hardness and glass transition temperature are Result-Effective variables. In light of which, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a polyurethane or polyurethane-urea with whatever hardness and/or glass transition temperature through routine experimentation in order to obtain a proper polyurethane or polyurethane-urea in the filed of application it will be used. Especially, Applicants do not show the criticalities of the specific hardness and the specific glass transition temperature. See MPEP 2144.05 (II).

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24. Claims 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito.

Ito discloses a polyurethane, supra, which is incorporated herein by reference. Ito is silent the specific hardness in terms of Shore D and the specific glass transition temperatures of the polyurethane or polyurethane-urea. Ito further teaches the use of the materials for making a film (page 3, second and third paragraph, page 4, third paragraph and page 6, second and third paragraphs and page 9, last paragraph) wherein the hardness and flexibility is important. Therefore, the hardness and glass transition temperature are Result-Effective variables. In light of which, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a polyurethane with whatever hardness and/or glass transition temperature through routine experimentation in order to obtain a proper polyurethane in the filed of application it will be used. Especially, Applicants do not show the criticalities of the specific hardness and the specific glass transition temperature. See MPEP 2144.05 (II).

25. Claims 77, 79-82, 101-104, 109-113, 117-121, 123-132, 137-146 and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward (US 5 814 705) in view of Gunatillake.

With respect to Claims 77, 79-82, 101-104 and 117-121, Ward discloses a shape memory polyether urethane used biomedical applications (col. 4, lines 26-52 and col. 4, line 64 to col. 5, line 10). Ward is silent on a specific polyether urethane. Gunatillake discloses a polyurethane composition comprising a polyurethane derived from i) a soft segment macrodiol, ii) a diisocyanate and iii) a chain extender or a chain extender composition. The soft segment macrodiol can be polyethers, as further exemplified in Examples. (page 3, line 25 to page 4, line 10, page 10, line 13 to page 11, line 9). The polyether macrodiols can be those described in page

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11, lines 2 to 13 and Examples. Gunatillake's composition can also be used in biomedical applications (page 14, line 6 to page 15, line 5). Since Gunatillake's disclosure is in the same field as that of the Ward's endeavor, it would have been obvious to one of ordinary skill in the art at the time of invention to use Gunatillake's polyether urethane in Ward's disclosure, and thereby obtain the present invention.

With respect to Claims 109-111, Gunatillake further teaches that the diisocyanate can be those described in page 11, lines 14-20.

With respect to Claims 112-113, Gunatillake further teaches that the chain extender can be the one described in page 4, lines 1-10, wherein R₇ can be the one described in page 4, lines 6-8 and page 7, lines 24-26. It can be used in combination with another chain extender such as 1,4-butanediol, etc. (page 9, lines 3-12).

With respect to Claims 123-124, Ward further teaches that the polyether urethane can have a lower glass transition temperature between about 20°C and about 60°C (col. 2, lines 40-59).

With respect to Claims 125-128, Ward further teaches that a plasticizer or a second polymer can be blended with the polyether urethane. (col. 3, lines 4-20 and col. 5, lines 25-32).

With respect to Claims 129-132, as mentioned previously, Ward further teaches that the polyether urethane can have a lower glass transition temperature of about 20°C. Ward further teaches the use of a phenoxy resin as the second polymer which has a glass transition of about 91°C (col. 5, lines 25-32). The final blend can desirably have a glass transition temperature of about 25°C to about 60°C (col. 6, line 56 to col. 7, line 7). Ward is silent on the amounts of the hard segments in the first polymer and in the second polymer. However, it is noted that the

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amount of hard segment in a polymer ultimately affects the glass transition temperature of the polymer. In other words, the amount of hard segment is a Result-Effective variable.

Furthermore, as mentioned above, Ward teaches a final blend with a desired final glass transition temperature. In light of which, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a blend of a first polymer and a second polymer each having whatever amount of hard segment through routine experimentation in order to obtain a blend with a desired glass transition temperature. Especially, Applicants do not show the criticality of the amounts of hard segments. See MPEP 2144.05 (II). Because of the 35 U.S.C. 112, second paragraph issue of Claim 132, *supra*, the instant claim is rejected here with the understanding that the instant claim is directed to a shape memory composition which includes a combination of an elastomeric polyurethane or polyurethane-urea and a non-elastomeric polymer, pending verification.

With respect to Claims 137-146 and 152, Gunatillake further teaches that the polyurethane composition has improved mechanical properties, clarity, processability, biostability and/or degradation resistance (page 13, line 11 to page 15, line 17).

26. Claims 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs405.

Meijs405 discloses a shape memory polyurethane, *supra*, which is incorporated herein by reference. Meijs405 is silent the specific hardness in terms of Shore D and the specific glass transition temperatures of the polyurethane. Meijs405 further teaches the use of the materials in the field of application such as biomaterials (page 4, line 1 to page 5, line 23) wherein hardness

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(i.e., soft ness) and flexibility (i.e., flexural modulus) of the materials are obviously very important (page 6, lines 18-22). Therefore, the hardness and glass transition temperature are Result-Effective variables. In light of which, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a polyurethane with whatever hardness and/or glass transition temperature through routine experimentation in order to obtain a proper polyurethane in the filed of application it will be used. Especially, Applicants do not show the criticalities of the specific hardness and the specific glass transition temperature. See MPEP 2144.05 (II).

27. Claims 94-100 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

None of the aforementioned references teaches or fairly suggest the use of the silicon-based polycarbonate represented by formula (IV) for making a shape memory polyurethane or polyurethane-urea polymer.

28. The certified copy of Australia PQ 1707 has not been received.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (703) 306-5550.

The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson, can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

klp
September 5, 2003



Kuo-Liang Peng
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